

# Exhibit 3

	ZHEJIANG HUAHAI PHARMACEUTICAL CO., LTD.	Date: 2007-09-20
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### 3.2.A APPENDICES

	ZHEJIANG HUAHAI PHARMACEUTICAL CO., LTD.	Date: 2007-09-20
	Valsartan	Version 1.0
Module: 3	Quality	
Module: 3.2.A.	Appendices	Confidential
Table of Contents		

## TABLE OF CONTENTS

<b>3.2.A APPENDICES.....</b>	<b>882</b>
<b>1. Introduction .....</b>	<b>885</b>
1.1 Address .....	886
1.2 Company Profile .....	887
1.3 Location in China .....	888
1.4 Location in Province .....	889
<b>2. Statement of Commitments .....</b>	<b>890</b>
2.1 Statement of Commitment on following of GMP .....	891
2.2 Statement of Commitment regarding non-infringement of Patent Laws .....	891
2.3 Statement of Commitment regarding effluent treatment and its disposal .....	891
2.4 Commitment to provide stability data .....	891
2.5 Statement on analytical methods validation .....	891
<b>3. Organization and Personnel .....</b>	<b>892</b>
3.1 Organization Chart .....	893
3.2 Personnel .....	894
3.3 Consultants and their Area of Expertise .....	896
<b>4. Buildings and Utilities .....</b>	<b>897</b>
4.1 Buildings .....	898
4.2 Utilities .....	899
<b>5. Equipment.....</b>	<b>900</b>
5.1 List of equipments .....	901
5.2 Flow chart of equipments .....	904
<b>6. Quality Assurance Department.....</b>	<b>908</b>
6.1 Organizational Chart for Quality Assurance Department .....	909
6.2 Principle Objectives .....	910
6.3 Responsibilities/Authority of QA.....	911
6.4 List of Instruments – Q.C.....	912
<b>7. cGMP Related to Manufacturing Operations .....</b>	<b>913</b>
7.1 Equipment Cleaning and Validation of Cleaning Procedures.....	914
7.2 Receipt, Sampling, Testing and Storage .....	914
7.3 Production and Process Controls.....	915
7.4 Calculation of Yield .....	915
7.5 Master Production Procedures.....	916
7.6 Batch Production Records .....	916

	ZHEJIANG HUAHAI PHARMACEUTICAL CO., LTD.	Date: 2007-09-20
	Valsartan	Version 1.0
Module: 3	Quality	
Module: 3.2.A.	Appendices	Confidential

**Table of Contents**

7.7 Packaging of Finished Goods.....	916
7.8 Label Control.....	917
7.9 Handling of Rejected Materials .....	917
7.10 Customer Complaint .....	918
7.11 Specifications for Process Water.....	918
7.12 Change Control.....	919
7.13 Out of Specification Investigations .....	919
7.14 Maintenance and Calibration .....	919
7.15 Safety .....	920
<b>8. Environmental Impact Analysis.....</b>	<b>926</b>
8.1 Environmental Control System .....	927
8.2 Consent Letter from Government Agency .....	928

	ZHEJIANG HUAHAI PHARMACEUTICAL CO., LTD.	Date: 2007-09-20
	Valsartan	Version 1.0
Module: 3	Quality	
Module: 3.2.A.	Appendices	Confidential
2.	<b>Statement of commitments</b>	

## **2.1 Statement of Commitment on following of GMP**

The holder certifies that we will observe Good Manufacturing Practices for methods used in, and the facilities or controls used for the manufacturing, processing, packing or holding of a drug as covered by this DMF to assure that such drug meets the requirements of ICH Q7A "Good Manufacturing Practice Guidance for Active Pharmaceutical Ingredients" as to safety, and has the identity and strength and meets the quality and purity characteristics that it purports or is represented to possess.

## **2.2 Statement of Commitment regarding non-infringement of Patent Laws**

The holder certifies that all of the manufacturing procedures and products will not infringe any Patent Laws. Before manufacturing of drug product, as per local laws, it is necessary to apply for the license of drug product. A license will not be issued by the local authorities if there is any infringement of Patent Laws.

## **2.3 Statement of Commitment regarding effluent treatment and its disposal**

The holder certifies that all the effluents will be treated in properly designed and well maintained effluent treatment facilities to bring the final effluents to the ecological standards prescribed by the local authorities. No adverse environmental impact is expected from the manufacture and distribution of the products manufactured by the company.

## **2.4 Commitment to provide stability data**

Accelerated temperature and long-term storage temperature stability data as defined by ICH Guidelines are included in this DMF. However, further stability data at long-term storage conditions will be provided as and when generated at the different stability periods.

## **2.5 Statement on analytical methods validation**

USP and in-house made methods are being used for the analysis of drug substance. Most of the methods of analysis described in this DMF are taken from USP. Therefore, validation of these methods was not carried out in our laboratory. For in-house made method, it was validated in our laboratory.

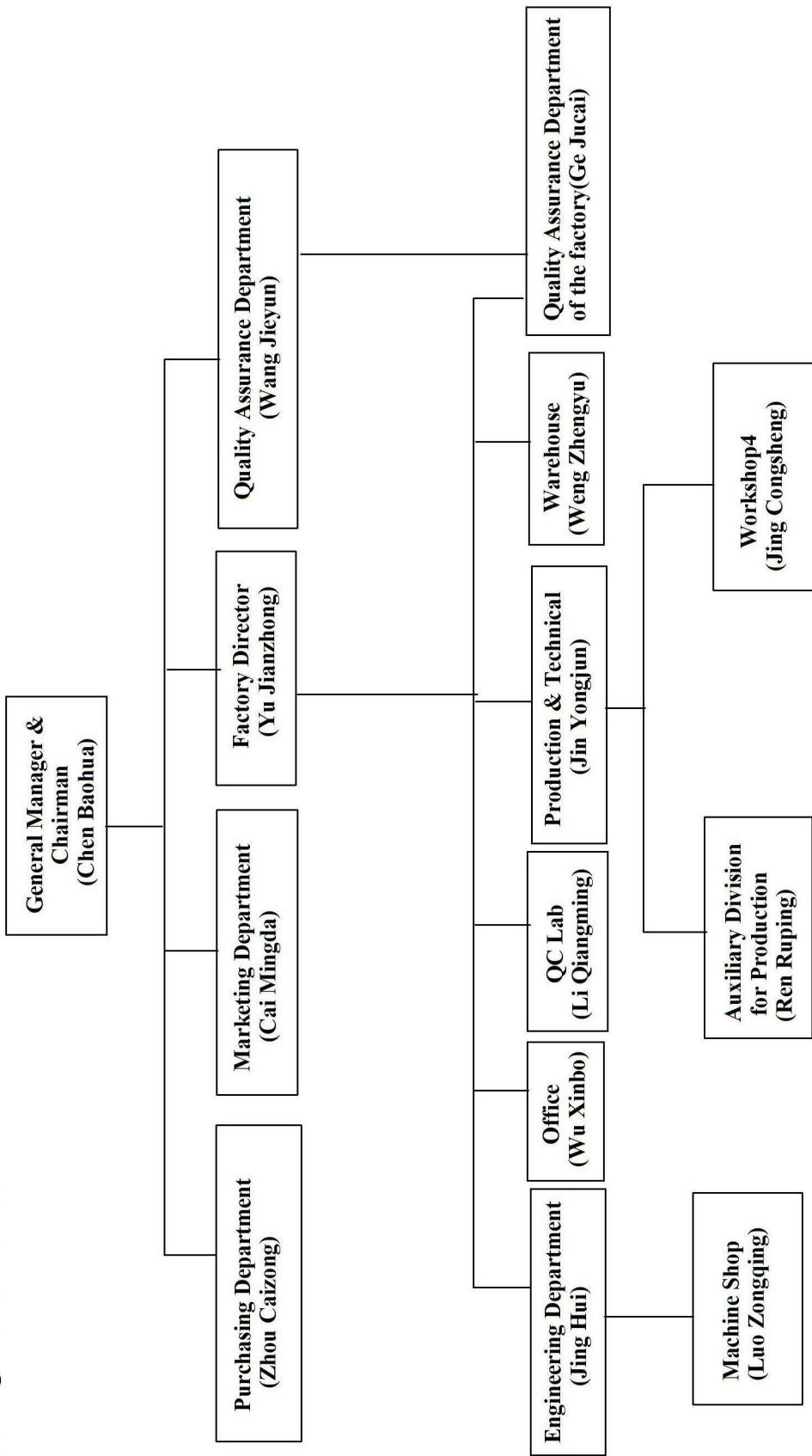
B.H. Chen  
General Manager  
Zhejiang Huahai Pharmaceutical Co., Ltd.

	ZHEJIANG HUAHAI PHARMACEUTICAL CO., LTD.	Date: 2007-09-20
	Valsartan	Version 1.0
Module: 3	Quality	
Module: 3.2.A.	Appendices	Confidential
3.	Organization and personnel	

### 3. Organization and Personnel

	ZHEJIANG HUAIHAI PHARMACEUTICAL CO., LTD.		Date: 2007-09-20
	Valsartan		Version 1.0
Module: 3	Quality		
Module: 3.2.A.	Appendices		
3.	Organization and personnel		

### 3.1 Organization Chart



	<b>ZHEJIANG HUAHAI PHARMACEUTICAL CO., LTD.</b>	<b>Date: 2007-09-20</b>
	<b>Valsartan</b>	Version 1.0
<b>Module: 3</b>	<b>Quality</b>	
<b>Module: 3.2.A.</b>	<b>Appendices</b>	<b>Confidential</b>
<b>3.</b>	<b>Organization and personnel</b>	

### 3.2 Personnel

- Mr. Baohua Chen  
Designation: Chairman and General Manager  
Qualification: Chemical Engineer  
Mr. Baohua Chen graduated from Zhejiang University of Technology in 1983 and worked in Zhejiang Haimen Pharmaceutical Factory from 1983 to 1989. He has worked in Zhejiang Huahai as General Manager since 1989. He has wide experience in the product development and quality management of bulk drugs.
- Mr. Jiangzhong Yu  
Designation: API and intermediate Plant Manager  
Qualification: Chemical Engineer  
Mr. Jianzhong Yu joined Huahai as administrative manager in 2001. He is responsible for production of all bulk drugs (including intermediates) at Zhejiang Huahai. He has wide experience in production management and plant maintenance.
- Mr. Yongjun Jin  
Designation: Factory Assistant Director  
Qualification: Professional Engineer  
Mr. Yongjun Jin obtained his degree from Zhejiang University of Technology in 1994. He joined Huahai in 1994. He has wide experience at production technology management and is responsible for the technology development of all bulk drugs at Zhejiang Huahai.
- Miss Jieyun Wang  
Designation: Quality Assurance Director  
Qualification: Professional Engineer  
Miss Jieyun Wang obtained her degree from Zhejiang Pharmaceutical University. She joined Zhejiang Huahai in 2000 as Quality Assurance Director. She is responsible for QA/GMP auditing and the QC/GMP file management for all products.
- Miss Jucai Ge  
Designation: Q.A. Supervisor  
Qualification: Assistant Engineer  
Miss Ge obtained her degree from Zhejiang University of Technology in 2000. She joined Zhejiang Huahai in 2000 and now she is working as Q.A. Supervisor and responsible for QA/GMP audits and the QA/GMP file management of API production at Chuannan No.1 Factory of Zhejiang Huahai Pharmaceutical Co., Ltd.
- Mr. Qiangming Li  
Designation: Q.C. director  
Qualification: Assistant Analytical Engineer

	<b>ZHEJIANG HUAHAI PHARMACEUTICAL CO., LTD.</b>	<b>Date: 2007-09-20</b>
	<b>Valsartan</b>	Version 1.0
<b>Module: 3</b>	<b>Quality</b>	
<b>Module: 3.2.A.</b>	<b>Appendices</b>	<b>Confidential</b>
<b>3.</b>	<b>Organization and personnel</b>	

Mr. Qiangming Li obtained his degree from Wuhan chemical college and joined Huahai in 1999 and now is working as QC director. He is responsible for analyses of raw materials, intermediates and final product.

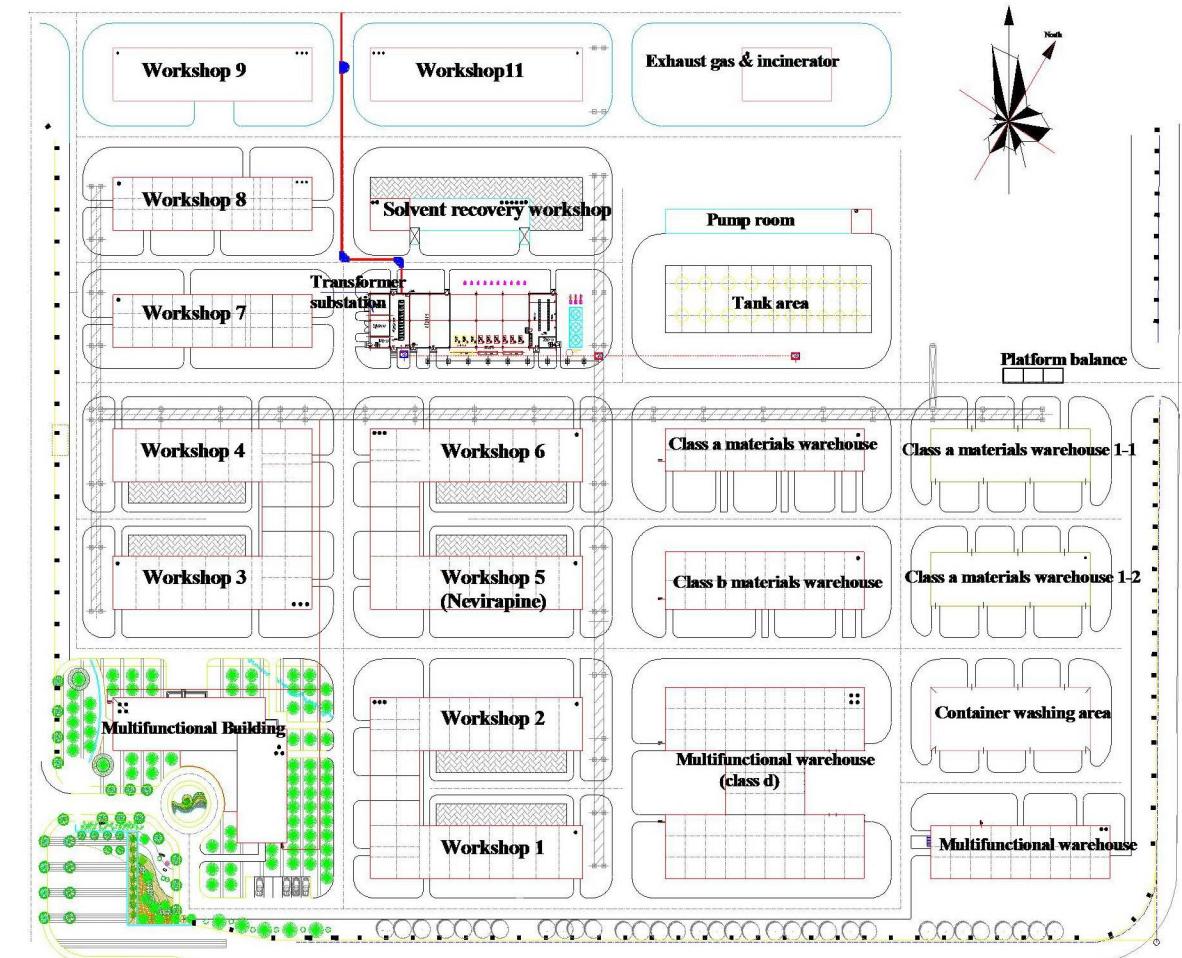
- Mr. Ruping Ren  
Designation: Auxiliary workshop director  
Qualification: Technician  
Mr. Ren graduated from Zhejiang University of broadcast television in 1996. He has 5-year experience at production and mechanical management and is responsible for management of auxiliary facilities.
- Mr. Congsheng Jin  
Designation: Valsartan workshop director  
Qualification: Technician  
Mr. Jin obtained his degree from Datian high school in 1983. He has 8-year experience at production management and is responsible for production of Valsartan.
- Mr. Youhu Wang  
Designation: Technology leader  
Qualification: Engineer  
Mr. Youhu Wang graduated from Zhejiang University of Technology in 2002 and joined Huahai upon graduation as technician; he is responsible for Valsartan.

	ZHEJIANG HUAHAI PHARMACEUTICAL CO., LTD.	Date: 2007-09-20
	Valsartan	Version 1.0
Module: 3	Quality	
Module: 3.2.A.	Appendices	Confidential
4.	<b>Buildings and Utilities</b>	

#### **4. Buildings and Utilities**

	ZHEJIANG HUAHAI PHARMACEUTICAL CO., LTD.	Date: 2007-09-20
	Valsartan	Version 1.0
Module: 3	Quality	
Module: 3.2.A.	Appendices	Confidential
4.	Buildings and Utilities	

#### 4.1 Buildings



	ZHEJIANG HUAHAI PHARMACEUTICAL CO., LTD.	Date: 2007-09-20
	Valsartan	Version 1.0
Module: 3	Quality	
Module: 3.2.A.	Appendices	Confidential
4.	Buildings and Utilities	

#### 4.2 Utilities

➤ Heat

The heat for manufacturing is supplied by steam from the Coastal Industrial Zone, the capacity is 15tons of steam per day.

➤ Waste Water Treatment: The capacity is 2500 tons of wastewater per day.

➤ Water

The water is city water treated and supplied by the government. Process water is used for later processing stages. It is tested at points of use for in-house chemical and biological specifications. Sampling/testing procedures with adequate frequency have been established.

➤ Electricity and Lights

Power is supplied by Linhai Power Company. All buildings are equipped with adequate lights.

➤ Ventilation

Exhaust fans have been installed wherever gas/odors are emitted and the waste gas is exhausted after treatment. Filtered air is circulated in areas where bulk drugs (API) are produced/packaged/handled.

➤ Maintenance (Buildings)

All buildings are maintained in good condition. Repairs are scheduled at regular intervals and the heads of each department are responsible for their maintenance. Outside contractors are employed to carry out repairs and maintenance to the buildings.

➤ Painting

The inside of the facility is painted once a year with synthetic resin paint. The outside buildings are painted every two years with a waterproof coating after defects are repaired.

➤ Cleaning

The entire premises are cleaned on a daily basis.

➤ Plumbing

Drains are cleaned regularly by the plumbers and their cleanliness is checked regularly by the production chemists.

➤ Buildings are protected from entry by birds, animals, etc. with proper doors and window screening.

	ZHEJIANG HUAHAI PHARMACEUTICAL CO., LTD.	Date: 2007-09-20
	Valsartan	Version 1.0
Module: 3	Quality	
Module: 3.2.A.	Appendices	Confidential
6.	Quality assurance department	

### 6.1 Organizational Chart for Quality Assurance Department

The Quality Unit, which is divided into QA, QC and QR, is lead by the General Manager independent from manufacturing and sales departments, covering all functions and actions necessary to provide adequate confidence that the finished product manufactured by the company will perform the intended purpose with regard to safety, purity and effectiveness.

The Quality Unit organization at Zhejiang Huahai Pharmaceutical Co., Ltd. is as follows:

